

PI 1177405

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TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

June 01, 2004

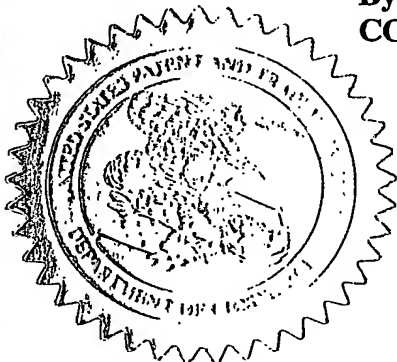
THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE.

APPLICATION NUMBER: 60/458,643

FILING DATE: March 28, 2003

RELATED PCT APPLICATION NUMBER: PCT/US04/09620

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS



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PROVISIONAL APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION under 37 CFR 1.53(c).

DOCKET NUMBER: B01075.70040
Express Mail Label No. EV 208 517 808 US
Date of Deposit: March 28, 2003

U.S. PTO
60458643
03/28/03

03/28/03
JC962 U.S. PTO

INVENTOR(S)/APPLICANT(S)

LAST NAME	FIRST NAME	MIDDLE INITIAL	RESIDENCE (CITY AND EITHER STATE OR FOREIGN COUNTRY)
Stevens-Wright	Debbie		North Andover, MA

☐ Additional inventors are being named on the separately numbered sheets attached hereto.

TITLE OF THE INVENTION (280 characters max)

METHOD AND APPARATUS FOR SELECTING TEMPERATURE/POWER SET POINTS IN ELECTROPHYSIOLOGY PROCEDURES

CORRESPONDENCE ADDRESS

CUSTOMER NUMBER:

23628

ENCLOSED APPLICATION PARTS (check all that apply)

- ☒ Specification - Number of Pages = 11
- ☐ Drawing(s) - Number of Sheets
- ☐ Application Data Sheet, See 37 CFR 1.76
- ☒ Return receipt postcard

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No
☐ Yes, the name of the U.S., Government Agency and the Government Contract Number are:

☐ Other:

METHOD OF PAYMENT (check all that apply)

- ☒ A check is enclosed to cover the Provisional Filing Fees.
- ☐ The Commissioner is hereby authorized to charge any additional fees or credit overpayment to Deposit Account 23/2825. A duplicate of this sheet is enclosed.
- ☐ Small Entity Status is claimed.

PROVISIONAL FILING FEE AMOUNT \$ 160.00

Respectfully submitted,

March 28, 2003
Date

James H. Morris, Reg. No. 34,681
Telephone No.: 617-720-3500

TITLE: Algorithm for determining target temperature

From Page No. 1

or target power or power control algorithm

Dependent

Depending upon the surface extension of electrode toward the boundaries of the ablation domain, the power requirements and the temperature sensing requirements will vary from one electrode design. In addition, the flow conditions and proximity of the electrode to the tissue surface will affect these requirements. Traditionally, a single set point has been applied across varying flow conditions, geometries and tissue electrode gaps. The proposed computer model includes an algorithm in which the set point's (power or temperature) would depend upon:

Impedance
Tissue Gap
Flow

The impedance at the start of ablation is dependent upon the surface geometry of the electrode. The impedance increases the outer surface of the electrode extends towards the boundary of the ablation domain. Larger electrodes requiring more power and have lower impedances.

*Larger tissue gaps, preferable at higher flows and smaller gaps preferable at lower flows.

The difference between tissue temperature and electrode temperature increases with increasing flow. Therefore a given design will require a lower set point at higher flows.

Below is an example of how the FEA analyses can be used to predict the temperature setpoint for known impedance, electrode geometry, tissue gap, flow, and flow.

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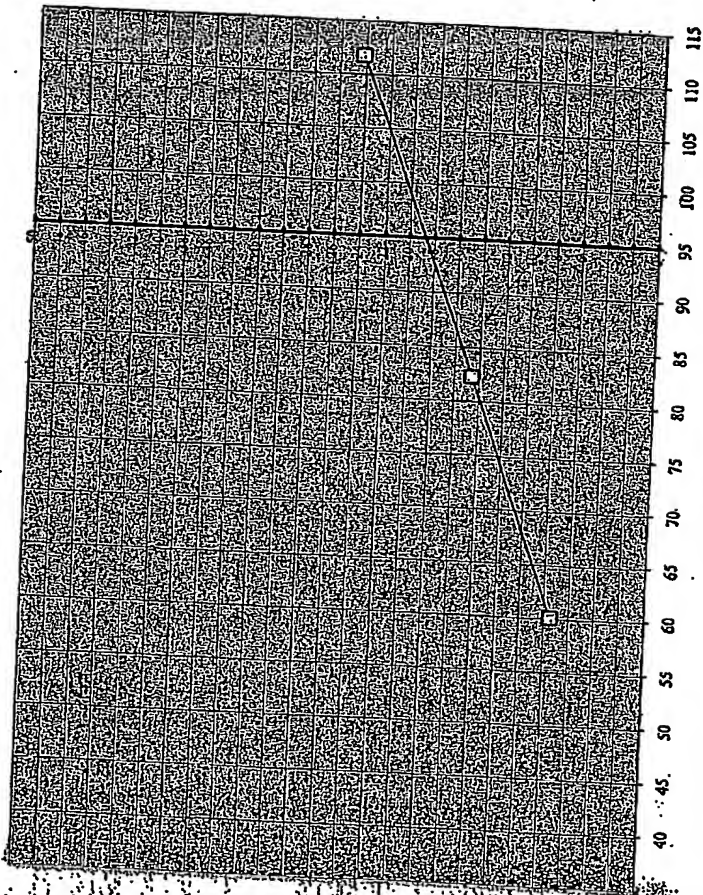
TITLE *Algebra - Temperature & Power Select*

From

TITLE

From 1

100
 95
 90
 85
 80
 75
 70
 65
 60
 55
 50
 45
 40



Temperature

115
 110
 105
 100
 95
 90
 85
 80
 75
 70
 65
 60
 55
 50
 45
 40

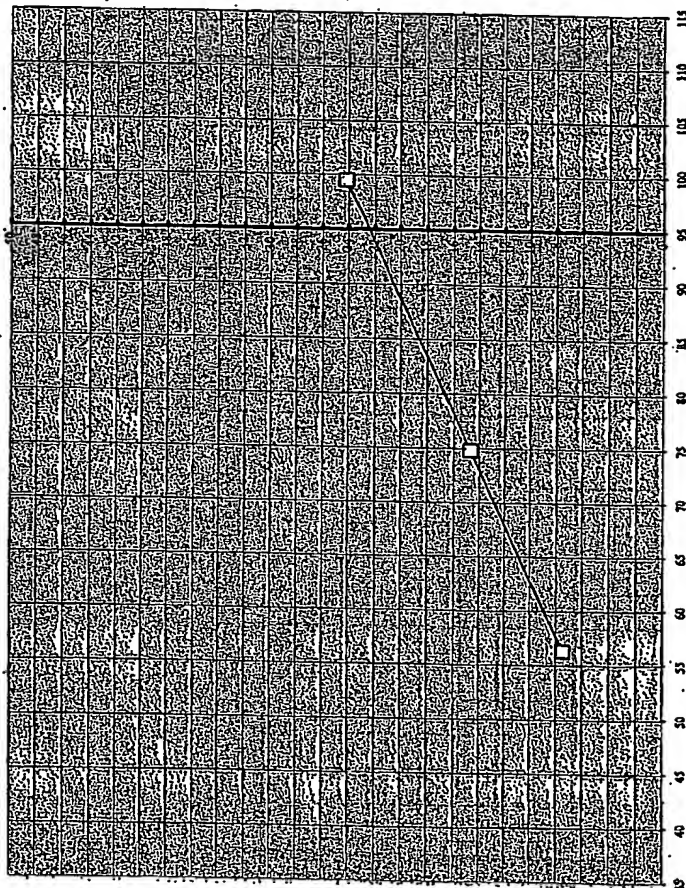
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TITLE: *Allografts & Temperature / Power Select*From Page No. *6*

SS-00-00

Power Select
Maximum Tissue Temperature
90 minutes



Tissue Temperature

Allografts & Temperature / Power Select

Page No. *6*

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TITLE: *Plumation - Temperature - Power - Shot*

TITLE

From F

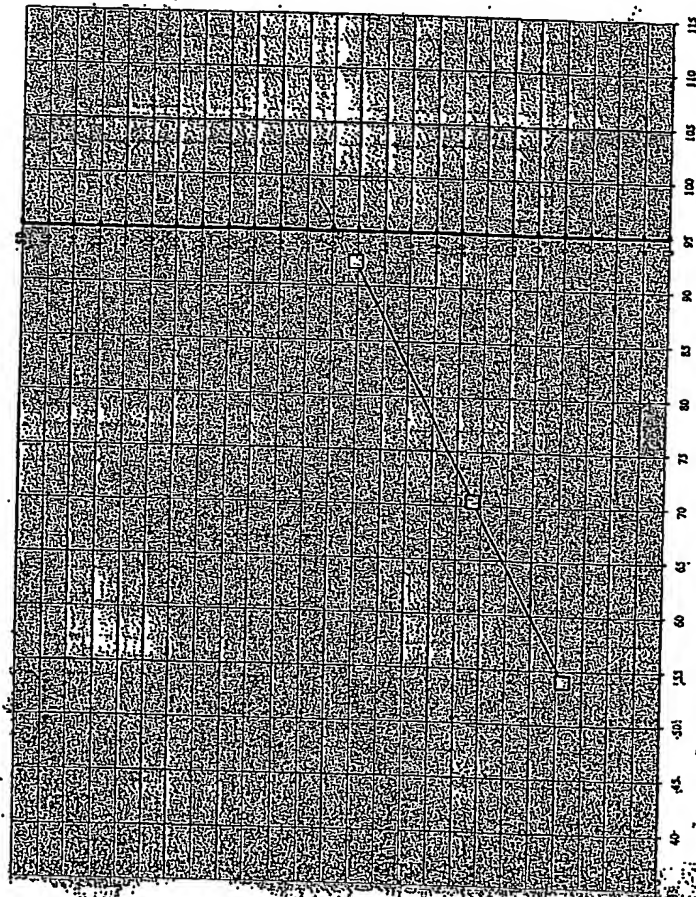
18

From F

85

Plumation - Temperature - Power - Shot

Plumation - Temperature - Power - Shot

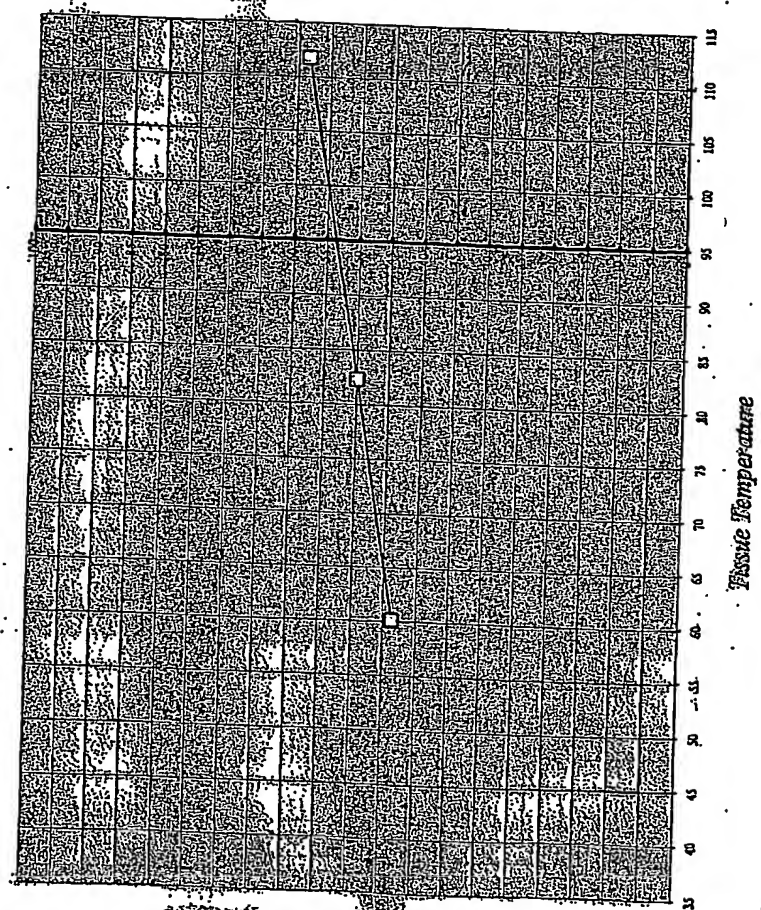


Plumation - Temperature - Power - Shot

Plumation - Temperature - Power - Shot

Page No.

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Excessive Temperature

Maximale Methode der Temperatur

No: _____

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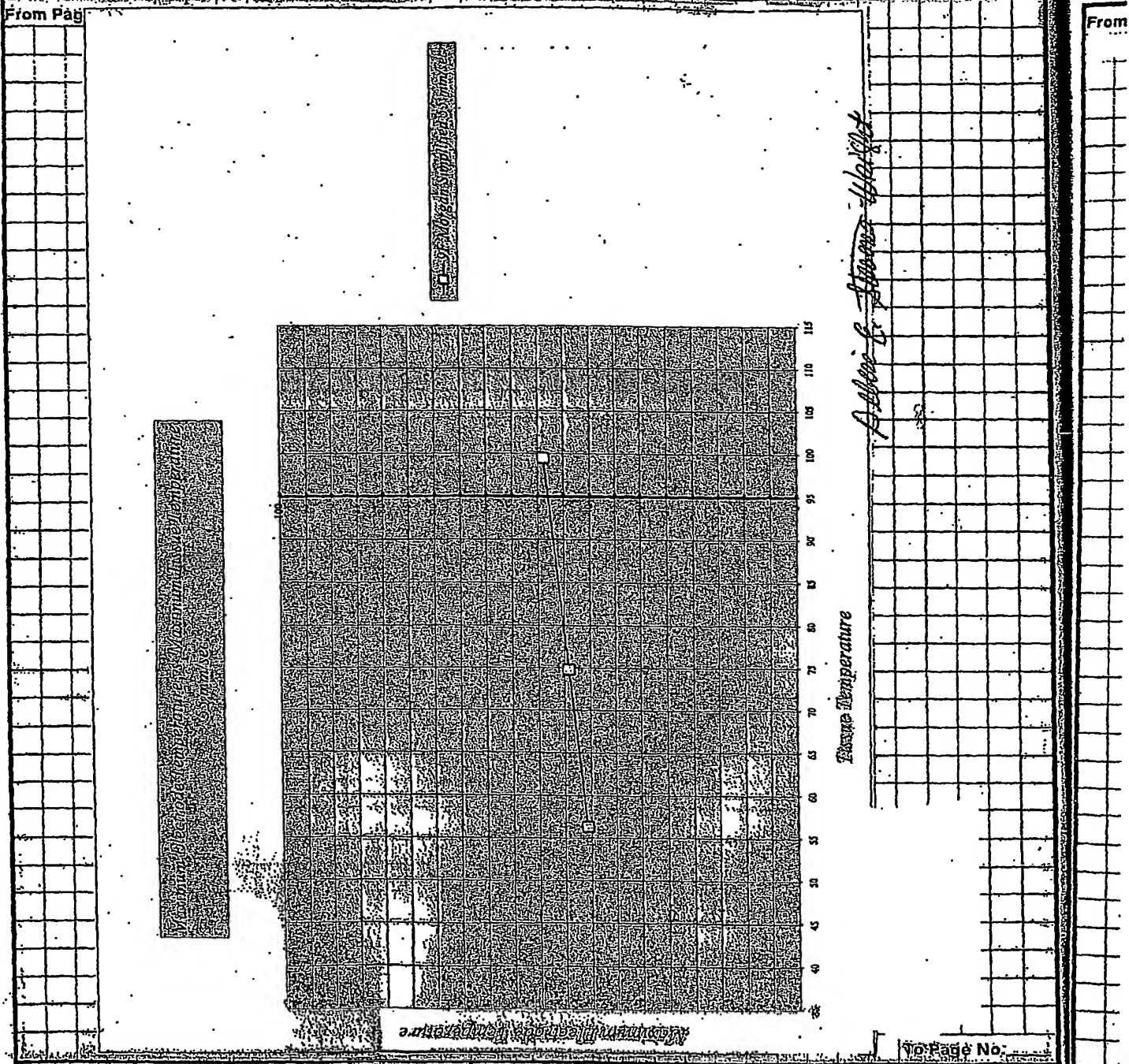
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TITLE *Algorithm - Temperature / Power Select*

TITL

From

From Page



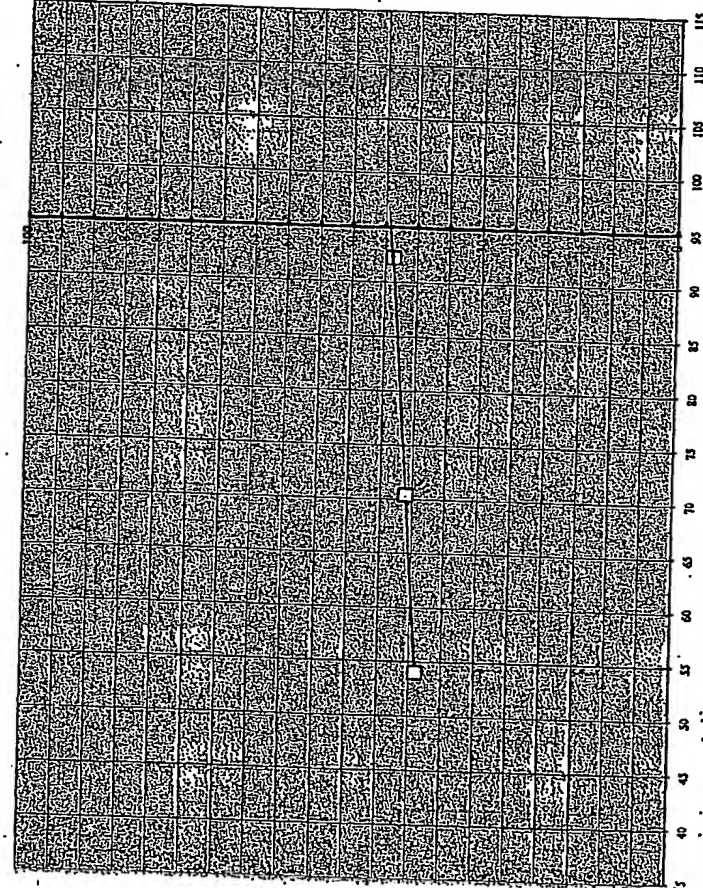
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TITLE: *Temperature of Power Cable*

Front Page No.

Page No.

Maximum Dielectric Temperature
Maximum Tissue Temperature
Maximum Tissue Temperature



Tissue Temperature

Debris & Tissue Masses

Maximum Dielectric Temperature

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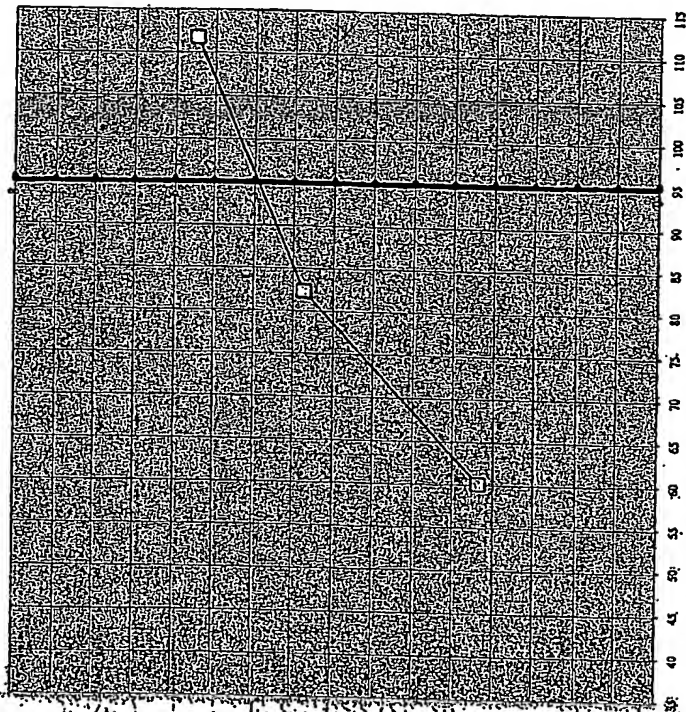
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TITLE: *Algorithms in Temperature / Power Select*

TITL

From

From Page

Algorithms in Temperature / Power Select

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From Page No. 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100 101 102 103 104 105 106 107 108 109 110 111 112 113 114 115 116 117 118 119 120 121 122 123 124 125 126 127 128 129 130 131 132 133 134 135 136 137 138 139 140 141 142 143 144 145 146 147 148 149 150 151 152 153 154 155 156 157 158 159 160 161 162 163 164 165 166 167 168 169 170 171 172 173 174 175 176 177 178 179 180 181 182 183 184 185 186 187 188 189 190 191 192 193 194 195 196 197 198 199 200 201 202 203 204 205 206 207 208 209 210 211 212 213 214 215 216 217 218 219 220 221 222 223 224 225 226 227 228 229 230 231 232 233 234 235 236 237 238 239 240 241 242 243 244 245 246 247 248 249 250 251 252 253 254 255 256 257 258 259 260 261 262 263 264 265 266 267 268 269 270 271 272 273 274 275 276 277 278 279 280 281 282 283 284 285 286 287 288 289 290 291 292 293 294 295 296 297 298 299 300 301 302 303 304 305 306 307 308 309 310 311 312 313 314 315 316 317 318 319 320 321 322 323 324 325 326 327 328 329 330 331 332 333 334 335 336 337 338 339 340 341 342 343 344 345 346 347 348 349 350 351 352 353 354 355 356 357 358 359 360 361 362 363 364 365 366 367 368 369 370 371 372 373 374 375 376 377 378 379 380 381 382 383 384 385 386 387 388 389 390 391 392 393 394 395 396 397 398 399 400 401 402 403 404 405 406 407 408 409 410 411 412 413 414 415 416 417 418 419 420 421 422 423 424 425 426 427 428 429 430 431 432 433 434 435 436 437 438 439 440 441 442 443 444 445 446 447 448 449 450 451 452 453 454 455 456 457 458 459 460 461 462 463 464 465 466 467 468 469 470 471 472 473 474 475 476 477 478 479 480 481 482 483 484 485 486 487 488 489 490 491 492 493 494 495 496 497 498 499 500 501 502 503 504 505 506 507 508 509 510 511 512 513 514

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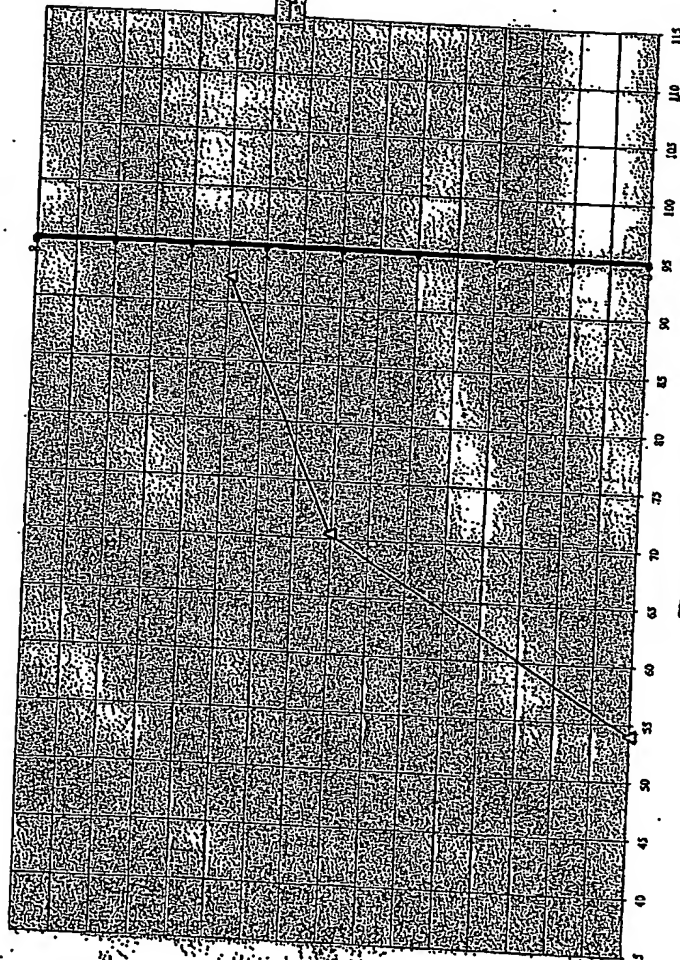
TITLE *Robert E. Algorithm - Temperature / Power*
52127

From Page No. _____

TIT

Fro

Maximum Tissue Temperature
65 mm/sec



Tissue Temperature

Robert E. Algorithm - Temperature / Power
52127

Page No. _____

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TITLE *Algorithm - Temperature / Power Selection*

From Page No. _____

Electrode - Ablation Prescription (Preliminary)					Expected Lesion Generation	
Flow	Impedance	Tissue Gap	Temperature Set Point	Power Set Point	mm	W
mm/sec	ohms	in.	°C			
30	83	.009 Embedded	54.0	18.8	4.93	
55	83	.009 Embedded	48.0	22.5	5.30	
85	83	.009 Embedded	44.5	26.0	5.65	

Do not E. Surged - Weight

The preceding curves were generated from an FEA analysis where the applied potential was ranged at three flow rates (30mm/sec, 55mm/sec, 85 mm/sec). The maximum allowable tissue temperature was chosen to be below 95°C. The set points were taken from plots of (Power vs Maximum tissue temperature) and (Maximum electrode temperature vs Maximum tissue temperature).

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